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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,625	06/02/2000	Carlos F. Barbas III	22908-1227B	6568

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,625	BARBAS ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8,10-35,37-39,41,42,44,46 and 69-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8,10-35,37-39,41,42,44,46 and 69-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/22/05, 2/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims

Examiner Joseph Murphy is no longer with the Office. Therefore, the Art Unit and Examiner prosecuting this application have been changed. Any inquiries relating to the examination of the application should be directed to Shulamith H. Shafer, Art Unit 1647.

Applicants have elected, without traverse, the sequence of nucleotides set forth in SEQ ID NO:1, in response of 18 April 2005. In Office Action of 5 December 2005, Examiner Murphy indicated that Claims 1-3, 5-6, 8, 10-27, 32-35, 37-39, 41-42, 44, 46, 69-89 were allowable.

The amendment received 28 February 2006 in response to Office Action of 5 December 2005 and the amendment received 18 May 2006 in response to the Notice of Non-Compliant Amendment, mailed 11 May 2006 have been entered. Claims 1-3, 5, 6, 8, 10-35, 37-39, 41, 42, 44, 46, 69-94 are pending in this application. Claims 28 and 29 have been amended, and the amendment has been entered. New claims 90-94 have been presented and entered. The Office recognizes that the application has undergone an extensive and lengthy prosecution. While full faith and credit is given to the previous examiners actions, new issues have been raised and the indicated allowability of claims 1-3, 5-6, 8, 10-27, 32-35, 37-39, 41-42, 44, 46, 69-89 is withdrawn.

Claims 1-3, 5, 6, 8, 10-35, 37-39, 41, 42, 44, 46, 69-94 are under consideration to the extent they read on the elected invention.

New issues are set forth below.

Information Disclosure Statement

References submitted on IDS filed 22 November 2005 are not in compliance with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 for the following reasons: Reference AA (on sheet 1 of 2) lists an incorrect first inventor. Reference AV (Sheet 2 of 2) has not been included with the instant application. Therefore this reference has been lined through and has not been considered.

All references submitted on IDS filed 28 February 2006, other than reference AA on sheet 1 of 2 have been lined through and have not been considered, as they are duplicates of the references listed on IDS submitted 22 November 2005.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

New Objections

Claims 90-93 are objected to as being duplicative of claims 28-31.

New Rejections

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, for example, *In re Berg*, 140 F.3d 1428 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim(s) 1-3, 5-6, 8, 10-35, 37-39, 41, 42, 44, 46, 69-73, 90-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim(s) 1-39, 41-51 of copending Application No. 10/422934. This is

a **provisional** obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claim 1 of the instant invention is drawn to a fusion protein, comprising a nucleotide-binding domain operatively linked to a modified ligand-binding domain from an intracellular receptor wherein the nucleotide-binding domain is a polydactyl zinc-finger that contains at least three modular portions and the ligand specificity of the LBD is modified whereby ligands that activate the fusion protein are not ligands that activate the receptor from which the LBD was derived. This claim is rendered obvious by claims 1, 4, 9, and 10 of the co-pending application (10/422934). Claims 2, 3, and 5 of the instant application are identical to claims 2, 3 and 5 of application 10/422934. Claim 6 of the instant invention is rendered obvious by claims 6 and 7 of application 10/422934; while the claims are not identical, they claim overlapping range of subject matter (sequence of nucleotides). Claims 8 and 10 of the instant invention are rendered obvious by claims 8-10 of application 10/422934; while the claims are not identical, they claim overlapping range of subject matter (modular units of zinc-finger protein). Claims 11 and 12 of the instant invention are identical to claims 11 and 12 of application 10/422934. Claim 13 of the instant invention is rendered obvious by claim 13 of co-pending application 10/422934. Claims 16-24 of the instant invention are identical to claims 16-24 of co-pending application 10/422934. Claim 25 and 94 of the instant invention is rendered obvious by claim 25 of application 10/422934; SEQ ID NO:1 of the instant invention is encompassed by claims to a nucleic acid molecule set forth in any of SEQ ID NOs:1-18. Claims 26 and 27 of the instant invention are identical to 26 and 27 of application 10/422934; claims 28-31, and 90-93 of the instant invention are rendered obvious by claims 28-31 of application 10/422934. Claim 32 of the instant invention is rendered obvious by claims 32 and 33 of application 10/422934. Claims 33-35, 37–39, 41, 42, 44 and 46 and are identical or rendered obvious by claims 32-39, 41, 42, 44 and 46 of co-pending application 10/422934. Claims 69-73 are identical or rendered obvious by claims 47-51 of application 10/422934.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 6, 8, 10-21, 23-31, 33, 34, 35, 37, 38, 39, 41, 42, 44, 46, 69-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting "polydactyl zinc-finger". It is unclear how a polydactyl (many-fingered) protein could be a single "zinc-finger". It is suggested that the claim be amended to read a "polydactyl zinc-finger domain". Additionally the claim recites "endogenous and exogenous ligands". It is unclear if "endogenous" refers to ligands inside the cell, those that are present in the organism or are ligands that are the physiological binding partners of a given ligand-binding domain. It is unclear if "exogenous" refers to ligands that are outside the cell or are artificial or non-physiological binding partners of a given ligand-binding domain. Furthermore, the claim recites "native hormone receptor". There is no antecedent basis for this; the first part of the claim is drawn to "an intracellular receptor". Claim 1 recites "at least about 3 nucleotides". This is vague and indefinite; in view of the low number of nucleotides recited, one would need more precise information of the number of nucleotides encompassed by this claim.

Claim 5 is vague and indefinite in reciting "substantially activated". This term is not defined in the specification; therefore the metes and bounds of the claim cannot be determined. Furthermore, the claim recites "endogenous ligands relative to exogenous or non-natural ligands". It is unclear if "endogenous" refers to ligands inside the cell, those that are present in the organism or are ligands that are the physiological binding partners of a given ligand-binding domain. It is unclear if "exogenous or non-natural" refers to ligands that are outside the cell or are artificial or non-physiological binding partners of a given ligand-binding domain.

Claim 20 is vague and indefinite in reciting "a transcription regulating domain that comprises a transcription repression domain." There is insufficient antecedent basis for this limitation, as Claim 1 only recites "the fusion protein is a ligand activated transcriptional regulator".

Regarding claim 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 34 and 37 are vague and indefinite in reciting "vector is derived from". It is unclear if vector is produced from a component of a DNA virus or a retrovirus or is a variant of a DNA virus or a retrovirus.

Claims 39, 41, 42, 44 and 46 are vague and indefinite in reciting "a combination". It is unclear if applicant intends invention to be a physical mixture, a composition, several compositions or a kit comprising a number of compositions.

Claim 72 is vague and definite in reciting a non-viral delivery system "wherein the non-viral delivery system is selected from the group consisting of .....direct injection of DNA, $CaPO_4$ precipitation, gene gun techniques, electroporation.....". These are all techniques for introducing DNA into cells, and are not delivery systems.

Claims 80 and 81 are vague and indefinite in reciting "wherein the second ligand binding domain is from an intracellular receptor is a nuclear hormone receptor.....". It is unclear what the metes and bounds of the claims are, as it appears that some words are omitted from the claim.

Claims 2, 3, 6, 8, 10, 11-19, 23-31, 35, 38, 69-71, 73-79, 82-93 are included in this rejection as dependent from rejected claims.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-35, 37, 38, 41 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 33-35, 37 and 38 are drawn to viral vectors wherein the viral vector is derived from a DNA virus or a retrovirus selected from the group consisting of an adenoviral vector, an adeno-associated viral vector, a herpes virus vector, a vaccinia virus vector and a lentiviral vector. The specification contemplates the use of the fusion proteins of the instant invention only within the context of gene therapy (page 53, lines 30 and 31 bridging page 54, lines 1-13). These claims are not enabled for the following reasons:

The art teaches that many problems remain with the use of gene transfer vectors. Kay et al (2001. Nature Medicine 7:33-40) teach that problems include "acute toxicity from the infusion of foreign materials, cellular immune responses directed against the transduced cells, humoral immune responses against the therapeutic gene

product, and the potential for insertional mutagenesis by certain integrating vectors" (page 34, 1st column, 1st paragraph). Thomas et al. (2003. Nature Reviews. Genetics. 4:346-358) teach the limitations of each of the disclosed vectors:

Retrovirus vectors only transduce dividing cells and integration might induce oncogenesis

Lentivirus vectors may induce oncogenesis upon integration into the genome

Herpes virus vectors induce inflammatory responses and may only induce transient transgene expressions in many cell types

Adeno-associated virus (AAV) vectors have only a small packaging capacity

Adenovirus vectors mediate potent inflammatory responses and have been responsible for patient death in clinical trial (page 351, Table 1).

Thomas et al. emphasize that "many of the immunological defense systems that are used to tackle wild-type infections are activated against the vectors and/or transgene products. Adenovirus vectors are the most immunogenic of all the viral vector groups (page 352, 2nd column, 1st paragraph). Even though other vector systems, such as the lentivirus vectors and AAV vectors are less inflammatory and immunogenic than adenovirus vectors, T-cell responses can still be elicited against expressed transgene product. Thomas et al. further teach that pre-existing humoral immunity to the parental wildtype virus is another obstacle that affects all classes of viral vector (page 353, 2nd column, last paragraph).

Due to the large quantity of experimentation necessary to determine which viral vector would be safe and effective to use for introducing a specific fusion protein into a specific tissue, organ or cell, the lack of direction/guidance presented in the specification regarding how to utilize vectors other than the adenovirus vector in a mouse model, the absence of working examples directed to the same, directed to same, the complex nature of the invention, the state of the prior art which establishes that tremendous amount of work needs to be done to improve the vectors available for gene therapy, and the breadth of the claims which fail to recite any limitations on the vectors to be utilized, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 44 recites the combination of claim 41, which recites a combination comprising a composition that "contains the fusion protein or nucleic acid molecule that encodes the fusion protein and the regulatable expression cassette in a pharmaceutically acceptable excipient" wherein the composition is formulated for "single dosage administration". Therefore, the claims recite an intended use (administration) and read on gene therapy. These claims are not enabled for the following reasons:

The specification contemplates the use of combinations for gene therapy, typically in vector suitable for gene therapy (page 9 lines 5-7). The specification teaches "the fusion proteins are administered either as a protein or as a nucleic acid encoding the protein and delivered to cells or tissues in a mammal" (page 66, lines 12-14) for treatment of "any genetic disease, for treatment of acquired disease and any other conditions" (page 66, lines 22-24). The claim broadly recites formulation for single dosage administration, but does not place any limits on the method of administration. The working examples (Example 19, especially pages 125-128) teach that the ZFP-LBD fusion proteins can be efficiently delivered via a single method of administration, an adenovirus vector and can be expressed in sufficient amounts, both in *in vitro* and *in vivo* systems, to provide high levels of drug-dependent control of a transgene in one animal model, a mouse model (page 128, lines 7-10). However, neither the specification nor the working examples provide sufficient guidance so that one of ordinary skill in the art could make or use the "combination comprising a nucleic acid molecule comprising a sequence of nucleotides that encodes the fusion protein and a regulatable expression cassette" in a pharmaceutically acceptable excipient for single dosage administration by any method of administration in any mammalian system without undertaking undue experimentation.

Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene therapy is to deliver DNA to the target tissues and to transport it to the cell

nucleus to enable the required protein to be expressed (Phillips, A.; pg 1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length of time (pg 1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express the claimed nucleic acid into any cell of any organism to treat an unspecified disease. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to introduce and express the claimed nucleic acid in the cell of an organism or be able to produce the encoded protein in that cell.

Due to the large quantity of experimentation necessary to introduce and express the claimed fusion protein or nucleic acid in any cell of any organism for therapy, the lack of direction/guidance presented in the specification regarding how to introduce the claimed nucleic acid, in ways other than using adenovirus vectors, in the cell of an organism to be able produce the encoded protein, the absence of working examples other than introduction of adenovirus vector into a mouse model system, directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of transferring genes into an organism's cells, and the breadth of the claims which fail to recite any limitations on methods of administration and organisms to be treated, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 10, 13, 15-19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to fusion proteins, encompassing a broad genus of molecules, comprising a nucleotide binding domain operatively linked to a modified ligand binding domain and further comprising an operatively linked transcription regulating domain, that comprise:

at least four zinc fingers or variants thereof,

wherein the modified ligand binding domain is from a progesterone receptor variant or an estrogen receptor variant, and

wherein the transcription regulating domain comprises a transcription activation domain selected from the group consisting of VP16, VP64, TA2, STAT-6, p65 and derivatives, multimers and combinations thereof and can bind the erbB-2 promoter; or

wherein the transcription activation domain comprises a nuclear hormone receptor transcription activation domain or variant thereof or wherein the transcription regulating domain comprises a viral transcription activation domain or variant thereof; or

wherein the transcription repression domain is selected from the group consisting of ERD, KRAB, SID, Deacetylase and derivatives, multimers and combinations.

The elected species is the fusion protein encoded by sequence of nucleotides set forth in SEQ ID NO:1.

Fusion proteins made up of variants of zinc-finger proteins, variants of the LBD domains of the estrogen and progesterone receptor other than the progesterone variants disclosed in Table 10 (page 106) or the estrogen variants, Av3-C7LBD-A(G521R) or Av3-C7LBD-B(G52R) (page 125, lines 8-10), derivatives, multimers, and combinations of variants VP16, VP64, TA2, STAT-6, p65, or derivatives, multimers and combinations of the transcription repression domain other than KRAB-ERD, SID-ERD, $(KRAB)_2$, $(KRAB)_3$, KRAB-A, $(KRAB\text{-}A)_2$, $(SID)_2$, (KRAB-A)-SID and SID-(KAB-A) do not meet the written description provision of 35 U.S.C. 112, first paragraph.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product or any combination thereof. In this case, there is not

identification of any particular portion of each of the components of the fusion protein that must be conserved, and only a recitation that the transcription activation activity of some of the variants must be preserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more that a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directe to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated fusion proteins polypeptides encoded by the nucleotide sequence of SEQ ID NO:1 or comprising the components identified above, but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Conclusions

Due to the new grounds of rejection herein, this action is made non final. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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